

**REMARKS**

**A. Regarding the Amendments**

Claims 1, 4, 5, 15, 27 and 46 have been amended as set forth in the attached "Version With Markings To Show Changes Made."

It is noted that the term "opacificant" has been amended to "opacifying" throughout the claims. the amendment has been made merely to clarify the word and is not narrowing in any manner.

As amended, the claims are supported by the specification and the original claims. Thus, upon entry of the amendments, claims 1 and 4-53 will be pending.

**B. Rejection Under 35 U.S.C. § 112**

Applicants respectfully traverse the rejection of claims 1, 6-23 and 27-53 under 35 U.S.C. § 112, first paragraph, for allegedly being non-enabled for polymerizable organic monomers in general, other than alkyl cyanoacrylates. It is respectfully submitted that the specification specifically discloses that the composition of the invention may comprise polymerizable organic monomers in general. See, for example, the specification at paragraphs [0009] and [0013]. However, in the interest of advancing prosecution, the language of claims 1, 27 and 46 has been amended to clarify that the claimed composition specifically comprises alkyl cyanoacrylate monomers.

As such, one of skill in the art would have been able to practice the present invention, as the amended claims specify a composition with a first component that includes at least two polymerizable alkyl cyanoacrylate monomers, and a second component that includes an oligomer of a polymerizable alkyl cyanoacrylate monomer, a plasticizer, and an opacifying agent. As it is stated by the Examiner in Paper No 6 that "the specification, [is] ...enabling for alkyl cyanoacrylates," claims 1, 6-23 and 27-53 meet the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, removal of the rejection is requested.

**C. Rejection Under 35 U.S.C. § 103**

Applicants respectfully traverse the rejection of claims 1-53 under 35 U.S.C. 103(a) as allegedly unpatentable over Evans in view of Tseng, Woodward, Clark, Hoffman, Krall, Almen, EP 0 747 069 and Leung.

In order for an invention to be obvious, the differences between the subject matter of the application and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art. In order to meet this standard, the combination of references must teach or suggest all of the elements of the claimed invention. It is respectfully submitted that Evans in view of Tseng, Woodward, Clark, Hoffman, Krall, Almen, EP 0 747 069 and Leung does not teach or suggest all of the elements of the claimed invention.

Evans, et al. discloses compositions and methods for embolizing blood vessels, "particularly suited for catheter delivery." However, Evans does not teach or suggest all of the elements of the present invention. While Evans does disclose treatment of arteriovenous malformations employing a biocompatible prepolymer, such as a cyanoacrylate, Evans does not teach or suggest use of more than one cyanoacrylate, nor does Evans teach a second component containing a cyanoacrylate oligomer. The present invention requires a combination of a first and second component, where the first component includes at least two polymerizable alkyl cyanoacrylate monomers, and the second component includes an oligomer of a polymerizable alkyl cyanoacrylate monomer, a plasticizer, and an opacifying agent. It is noted that the first component must contain a minimum of at least two polymerizable alkyl cyanoacrylate monomers. Additionally, the plasticizer of the second component serves to render the resulting polymer of the invention flexible. (Specification, page 16.) Such flexibility allows placement of the compositions and inhibition of breakage of the polymer, that may enter the bloodstream and cause a catastrophic event. As Evans does not teach or suggest all of the elements of the present invention, it is respectfully submitted that the present invention is not obvious in light of Evans.

Tseng, et al., Woodward, Clark, et al., Hoffman, Krall, Almen et al., EP 0 747 069 and Leung et al. do not teach or suggest adding a second polymerizable alkyl cyanoacrylate monomer or adding a second component of an oligomer of a polymerizable alkyl cyanoacrylate monomer, plasticizer and opacifying agent to the biocompatible prepolymer of Evans. As such, Evans, in light of Tseng, et al., Woodward, Clark, et al., Hoffman, Krall, Almen et al., EP 0 747 069 and Leung et al. does not teach or suggest all of the elements of the present invention.

Specifically, Tseng discloses 2-cyanoacrylates widely used in surgical fields, however Tseng does not teach or suggest the combined use of multiple cyanoacrylates in a composition or addition of a second component comprised of an oligomer of a polymerizable alkyl cyanoacrylate monomer, a plasticizer, and an opacifying agent.

Similarly, while Woodward discloses hexyl 2-cyanoacrylate and evaluates its properties *in vivo*, it does not teach or suggest the combination of the present invention. The teachings of Clark and Hoffman also do not teach or suggest a composition of two components, where the first component contains at least two polymerizable alkyl cyanoacrylates and the second component contains an oligomer of a alkyl cyanoacrylate monomer, a plasticizer and an opacifying agent. Also, Almen, while it contains a brief discussion of cyanoacrylates, does not teach the composition of the invention. EP 0 747 069 and Leung et al. also do not teach or suggest the composition of the invention.

The references cited in Paper No. 6 do not teach or suggest a composition of a first and second component, where the first component contains at least two polymerizable alkyl cyanoacrylates and a second component containing an oligomer of a polymerizable alkyl cyanoacrylate, a plasticizer and an opacifying agent. As such, the present invention is not obvious in light of Evans, et al. in view of Tseng, Woodward, Clark, Hoffman, Krall, Almen, EP 0 747 069 and Leung. It is therefore respectfully requested that the rejection be removed.

In re Application of:

Krall et al.

Application No.: 09/863,825

Filed: May 23, 2001

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**D. Double Patenting Rejection**

Applicants acknowledge the rejection of claims 1-53 under the judicially created doctrine of obviousness-type double patenting over claims 1-5 of U.S. Patent No. 6,037,366 in view of Evans, Krall, Almen, EP 0 747 069 and Leung. Applicants enclose herein a terminal disclaimer over commonly owned U.S. Pat. No. 6,037,366, to which priority is claimed in the present application under 35 U.S.C. §120. As the primary reference of this double patenting rejection is no longer available as prior art by virtue of the enclosed terminal disclaimer, it is respectfully submitted that the double patenting rejection of claims 1-53 under the judicially created doctrine of obviousness-type double patenting over claims 1-5 of U.S. Pat. No. 6,037,366 in view of Evans, Krall, Almen, EP 0 747 069 and Leung is moot. None of Evans, Krall, Almen, EP 0 747 069 or Leung teach the compositions or methods claimed in the present invention. Applicants respectively request withdrawal of the rejection.

Similarly, Applicants acknowledge the provisional rejection of claims 1-53 as unpatentable under the judicially created doctrine of obviousness-type double patenting, in light of the claims in co-pending Applications No. 09/823,775, 09/241,368, 09/497,075, 09/577,115 each in view of Evans, Krall, Almen, EP 0 747 069 and Leung. Applicants submit herein a terminal disclaimer over commonly owned Application Serial Nos. 09/823,775, 09/241,368, 09/497,075 and 09/577,115, to which priority is claimed in the present application under 35 U.S.C. §120. It is noted that co-pending Application No. 09/823,775 is an application for reissue of U.S. Pat. No. 6,037,366. As any patent granted on the reissue application will also be numbered as U.S. Pat. No. 6,037,366, it is noted that the terminal disclaimer to U.S. Pat. No. 6,037,366 will also apply to any patent resulting from the reissue application. However, in the interest of advancing prosecution, the terminal disclaimer of the co-pending applications includes Application No. 09/823,775. Accordingly, Applicants respectively request withdrawal of the rejection in view of the terminal disclaimer.

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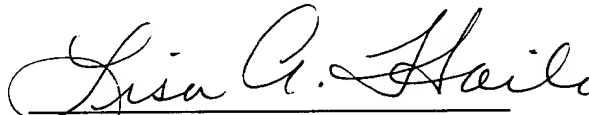
### CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1 and 4-53 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

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In re Application of:

Krall et al.

Application No.: 09/863,825

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Paragraph [0001] has been amended as follows:

--[0001] This application is a continuation-in-part of U.S. Serial No. 09/577,115, filed May 23, 2000, which is a continuation-in-part of U.S. Serial No. 09/497,075, filed February 9, 2000, now allowed, which is a continuation-in-part of U.S. Application Serial No. 09/241,368, filed January 29, 1999, the entire contents of all of which are incorporated herein by reference. The present application also claims priority to U.S. Serial No. 09/151,621, filed September 11, 1998, now issued U.S. Patent 6,037,366, which claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 60/058,510, filed September 11, 1997, all of which are [which is] incorporated herein by reference in [its] their entirety.--

IN THE CLAIMS:

1. (Amended) A composition comprising a first component and a second component, wherein said first component includes at least two polymerizable [organic] alkyl cyanoacrylate monomers, and wherein the second component includes an oligomer of a polymerizable [organic] alkyl cyanoacrylate monomer, a plasticizer, and an [opacificant] opacifying agent, wherein the composition polymerizes upon contact with an anionic environment.
4. (Amended) The composition according to claim [2] 1, wherein said alkyl cyanoacrylates of the first component are chosen such that the alkyl chain contains from 1 to 18 carbon atoms.
5. (Amended) The composition according to claim [2] 1, wherein said cyanoacrylates are selected from methyl cyanoacrylate, n-butyl cyanoacrylate, isobutyl cyanoacrylate, n-hexyl cyanoacrylate, 2-hexyl cyanoacrylate, n-octyl cyanoacrylate, or 2-ethylhexyl cyanoacrylate.
15. (Amended) The composition according to claim 14, wherein said esterified fatty [acids are] acid is chosen from the group consisting of laurates, palmitates, oleates, myristates, or stearates.

17. (Amended) The composition according to claim 1, wherein said [opacificant] opacifying agent is a metal.

27. (Amended) A method of filling, occluding, partially filling, or partially occluding an unfilled volume or space in an anionic environment, said method comprising, administering a composition comprising a first component and a second component, wherein said first component includes at least two polymerizable [organic] alkyl cyanoacrylate monomers, and wherein said second component includes an oligomer of a polymerizable [organic monomers] alkyl cyanoacrylate monomer, plasticizer, and an [opacificant] opacifying agent, wherein said composition polymerizes upon contact with said anionic environment when administered with a device comprising a means for stabilizing fluid flow distal or proximal to said space and a means for delivering said composition to said space, whereby said space is filled, occluded, partially filled, or partially occluded.

46. (Amended) A method of filling, occluding, partially filling, or partially occluding an unfilled volume or space in an anionic environment, said method comprising administering a composition comprising a first component and a second component, wherein said first component includes at least two polymerizable [organic] alkyl cyanoacrylate monomers, and wherein said second component includes an oligomer of a polymerizable [organic] alkyl cyanoacrylate monomer, a plasticizer, and an [opacificant] opacifying agent, wherein said composition polymerizes upon contact with said anionic environment when administered with a device comprising a temporary inflatable balloon and a catheter, whereby said space is filled, occluded, partially filled, or partially occluded.